2) REFRACTIVE SURGICAL PROCEDURES[1]

## A. RADIAL KERATOTOMY (RK)

### a. GENERAL CONSIDERATIONS

Up until the early to mid 1990's, the most common surgical technique to correct myopia was radial keratotomy (RK). Although RK has been eclipsed by more advanced procedures, the guidelines presented here are intended to assist in evaluating candidates who underwent vision correction prior to the advent and approval of PRK and LASIK.

RK involves cutting a set of 4-8 spoke-like incisions on the cornea, beginning near the pupil and extending toward the limbus. The incisions weaken the structure of the cornea, resulting in a flattening of the central portion. Several long-term follow-up studies have shown that most who have undergone this procedure are able to see adequately without correction. The largest such study is the ongoing Prospective Evaluation of Radial Keratotomy (PERK), which followed about 400 individuals for ten years. Ten years after surgery, 70% of PERK participants reported no need for glasses and 85% had uncorrected acuity of 20/40 or better (Waring, et al., 1994).

The acceptability of RK for patrol officer candidates depends on the following four considerations:

1) Post-RK impairment of visual function: About 3% of individuals experience a loss of two or more lines of best spectacle-corrected visual acuity (Waring, et al., 1991). However, candidates with unacceptable corrected vision can be readily identified during routine vision testing.

   Of greater concern are problems that are difficult to detect with routine testing, such as glare disability and impaired vision under dim conditions (Atkin, et al., 1986). The prevalence and severity of most of these problems is unknown. In addition, many individuals report the presence of "starbursts" - radiating lines around focal light sources such as headlights or streetlights. This is thought to be due to the scattering of light from the portions of the radial scars that extends over the dilated pupil (Waring, et al., 1991). Most individuals report that this does not interfere with their normal activities, but some have stated that it severely disrupts their night driving ability.

2) Stability of the uncorrected vision: Deterioration of visual function can occur either due to loss of surgical correction (increasing myopia known as regression) or surgical over-correction (progressive hyperopia).

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Significant regression ultimately occurs in about 25% of RK patients (Waring, et al., 1990). However, in 85% of these cases, the failure of the procedure is evident within the first six months after surgery (Waring, et al., 1990). After six months, the probability of developing ≥ -1.00 D of myopic error is 1.4% within the next 18 months, and increases to only 3.4% after 10 years (Waring, et al., 1994).

In contrast, surgical over correction does not usually begin to develop until 6-12 months after the procedure. Between 6 and 12 months post-op, 5% of patients will experience an MR change of ≥ +1 D (Waring, et al., 1994). This percentage steadily increases to 43% by 10 years post-op (Waring, et al., 1994).

Unfortunately, it is not possible to accurately predict and disqualify candidates who will experience a deterioration of visual function. However, given the high prevalence of this problem, a program of annual vision testing of officers who have undergone RK is advisable.

3) Diurnal variations: Post-RK patients commonly complain that their vision becomes progressively worse later in the day. Unfortunately, screening for this complication using traditional cutpoints for clinically significant changes (i.e. MR change of ≥ -0.50 D, or loss of two Snellen lines) has a low sensitivity[2] (42% and 24%, respectively) [Schanzlin, 1986]. For this reason, record review is essential when evaluating this potential complication. Any complaints of diurnal variation can be taken as sufficient proof that this problem exists, even if not confirmed by objective testing.

Note that significant diurnal variation may not develop until years after surgery. For example, McDonnell, et al. (1996) found that 10% of those who did not have a diurnal fluctuation at 3.5 years developed fluctuation of 2 lines or more at 11 years post-op. This observation lends further support to a program of annual vision testing after hire.

4) Risk of significant eye trauma: Results of animal and human studies have demonstrated that RK incisions weaken the structural integrity of the cornea and increase the risk of rupture with blunt trauma. This has been observed not only in the early post-op years (Schanzlin, et al., 1986), but also in patients who were 7-10 years post-op (Lee, et al., 1995; Vinger, et al., 1996). Many ophthalmologists who consult for professional sports teams now recommend use of protective glasses for contact sports (Groves, 1996). Although catastrophic, agencies should determine the actual likelihood of this type of injury to their patrol officers (e.g., by reviewing workers' compensations records) before using this as a basis for disqualification.

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[2] "Sensitivity" refers to the test's likelihood of actually identifying individuals who have a particular disease/condition.

b. RECOMMENDED EVALUATION PROTOCOL

The physician must carefully question the candidate about problems regarding glare, starbursts, night vision, and diurnal variation. Dates of surgeries and any repeat procedures ("touch-ups"or enhancements) should be noted. All records related to the surgery and follow-up care should be obtained.

All post-RK candidates should be required to submit the results of an eye examination from a private vision specialist. At a minimum, testing should include measurement of uncorrected and corrected far acuity and manifest refraction in the early a.m. and late p.m. in each eye. The candidate's vision should meet applicable guidelines at all times of day.

After this information is obtained, the physician should evaluate whether the candidate fulfills all of the following criteria for unrestricted duty:

- The candidate currently meets all applicable vision guidelines by objective testing at all times of the day.

- No record or history of difficulty with glare or night vision over the past several years.

- No significant diurnal instability in visual testing or function. The generally accepted criteria for significant visual instability is either a change of greater than one line (or >5 characters) of far acuity, or a change of >0.50 D in MR. However, since these objective criteria have limited sensitivity in detecting even moderate to severe diurnal fluctuation in visual function, documentation of complaints in medical records should be given greater weight than the results of current testing.

A candidate who meets these guidelines should be required to sign a pre-placement agreement, specifying that the agency has the authority to require yearly vision testing to ensure that the individual has not developed significant diurnal variation, myopic regression, or progressive hyperopia.

NOTE: Candidates with unsuccessful RK who use soft contact lenses (SCL) should be evaluated using the agency standards for both RK and SCL use. Specific examinations for neovascularization of the incisional scars should also be conducted. Vascularization of one or more scars for at least 25% of its length is considered significant (Waring, et al., 1991), and therefore a contraindication to continued SCL use. Progressive hyperopia should also be considered a contraindication to SCL use, since this condition may be exacerbated by SCLs (Edwards & Schaefer, 1987).

SUMMARY:

- All post-op records must be submitted for review;
- No significant difficulty/history of glare or night vision over past several years;
- No significant diurnal instability in visual testing or function.

## B. PHOTOREFRACTIVE KERATECTOMY (PRK)

### a. GENERAL CONSIDERATIONS

In the mid-90's, a laser-based surgical technique known as photorefractive keratectomy (PRK) largely replaced RK. In PRK, an excimer laser is used to reshape the surface of the cornea by cutting through the epithelium and ablating portions of the underlying corneal stroma. The epithelium grows back in 48-72 hours, and healing continues over the next 1-3 months. This procedure offers advantages over RK in that it does not significantly weaken the cornea nor increase the risk of rupture secondary to blunt trauma. However, corneal reaction to the laser can cause a reactive haze, resulting in night halos, starbursts, glare intolerance, and decreased contrast sensitivity. These complications can particularly interfere with the ability to safely drive at night (O'Brart, 1994). Typically, these complications develop several weeks after the procedure, reaching maximum severity between 3-6 months post-op, then fade away by one year post-op (Helmy, 1996; Wang, 1997).

The longest available follow-up study reexamined 83 patients after six years (Stephenson, et al., 1998). This study found no further regression of the refraction after the first year. There were no signs of hyperopic shift or diurnal variation, and corneal haze appeared to reduce over time. However, 7% of patients still evidenced observable haze on slit-lamp examination. This was associated with a loss of best-corrected visual acuity. Although night halos remained a significant problem for only 11% of the patients, all complained of halos at 18 months post-op, and had pupil sizes >5 mm. In this study, all patients were treated with a 4 mm ablation zone, which is relatively small. Larger ablation zones would be expected to cause fewer problems with halos.

### b. RECOMMENDED EVALUATION PROTOCOL

The physician must carefully question the candidate regarding problems of glare, night vision and halos. Dates of surgeries and any repeat procedures ("touch-ups" or enhancements) should be noted. Records related to the surgery and follow-up care should be obtained.

This information should be evaluated against the following criteria:

- The candidate currently meets all applicable vision guidelines by objective testing at all times of the day.
- The candidate is at least 6 months post-op.
- There is no history of significant symptomatology persisting after 1 year post-op based on review of records and history.

SUMMARY:

- All post-op records must be submitted for review;
- Meets all applicable vision guidelines at all times of day;
- The candidate is at least 6 months post-op;
- No history of significant symptomatology persisting after 1 year post-op.

## C. LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK)

### a. GENERAL CONSIDERATIONS

In the late 1990's, PRK was largely replaced by Laser-Assisted *In Situ* Keratomileusis (LASIK). LASIK is less painful, requires less recovery time, and is more effective for patients with higher degrees of myopia (3-10 D). LASIK differs from PRK in that it is a two-step procedure in which the laser is applied to the mid-corneal stroma rather than the surface. This is accomplished by first cutting a thin corneal flap that is folded back and then repositioned after the laser has reduced the corneal curvature.

Relative to PRK, haze is a less-common problem after LASIK. However, other post-LASIK problems are more common (e.g., moderate-to-severe halos [Pop, 2000]) or unique to this procedure (e.g., monocular diplopia [double vision when one eye is closed]). Post-LASIK symptoms commonly involve problems in low light conditions (Sugar, et al., 2002), stability of treatment effect over time, and traumatic injury to the corneal flap (Patel, 2001; Iskander, 2001; Sridhar, 2001). This and other visual disturbances associated with LASIK are described at http://www.fda.gov/cdrh/lasik and www.lasikinstitute.org/risk.html.

The prevalence of post-LASIK symptoms in one recent study is presented in the Table 1 (McDonald, 2001). In this study, the most common complaint six months after LASIK was related to driving at night; 6-14% of patients reported that this police-related task was significantly more difficult than before the surgery.
TABLE 1:

Summary of (Post-LASIK) Symptoms Reported Significantly Worse at 6 Months[a,b]

| | % Spherical Myopia n = 142 | % Myopia with Astigmatism n = 109 |
|---|---|---|
| Night driving difficulty | 6.4 | 13.8 |
| Glare | 3.5 | 9.2 |
| Halos/starbursts | 4.2 | 6.4 |
| Light sensitivity | 2.8 | 5.5 |
| Dryness | 4.2 | 2.8 |
| Fluctuation of vision | 2.1 | 1.8 |
| Blurring of vision | 2.1 | 0.9 |
| Redness | 0.7 | 1.8 |
| Double vision | 0.7 | 0.0 |
| Headache | 0.7 | 0.0 |

[a] Some subjects may represent more than one symptom.

[b] None of the following symptoms were reported as significantly worse: pain, burning, excessive tearing, and gritty feeling.

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While the examining physician can question the applicant regarding these symptoms and review medical records, more objective testing would seem to be warranted to ensure that the essential duties of patrol work can be done safely and efficiently. However, at the present time, there is no special testing that can reliably and objectively measure the presence, severity, and/or the functional significance of these symptoms.

Determination of minimum deferral period following surgery depends on the time course of (a), symptoms, (b) complications, and (c) regression of the surgical effect:

a) Symptoms: A review of several FDA approval studies involving thousands of patients indicates that the vast majority of symptoms develop very early in the post-surgical period, reaching its peak in the first weeks post-op (Autonomous Technologies Corporation, 2000; Nidek Technologies Inc., 2000; Bausch & Lomb Surgical, Inc., 2000; Summit Technologies, Inc., 1999). Therefore, in the absence of symptoms at one month post-op, there would be little justification for further deferral based on this consideration alone.

b) Complications: Similarly, the vast majority of significant surgical complications should be evident at one month post-op. One exception would be ectasia, or bulging of the cornea due to excessive thinning. Ectasia can develop months after surgery, but is seen primarily in patients with treatments above 10 D.

c) Regression of surgical effect: The time course for the regression of the surgical effect appears to be related to the amount of correction attempted. Most patients experience regression for only a few weeks. However, some patients with high myopia can progressively regress for months to years. For example, in one FDA approval study, only 5% of patients whose pre-op manifest error was 7 D had >1 D of regression between the 1st and 3rd months post-op (Summit Technologies, Inc. FDA Approval Application, 1999). This compared to 13% of patients with pre-op errors of >7 D. This study also found that 12% of patients

with > 7 D pre-op lost >1 D between 3 and 6 months. In a different study involving patients with 9-25 D pre-op, continuous myopic regression was observed for over two years (Han, 2000). The average regression at two years post-op was over 2.6 D. In patients with 10 D pre-op, Knorz (1998) found that 20% will regress by >1 D between the 1st and 12th post-op month.

b. RECOMMENDED EVALUATION PROTOCOL

The physician must carefully question the candidate about problems regarding glare, double vision, night vision, and halos. Dates of surgeries and any repeat procedures ("touch-ups" or enhancements) should be noted. All records related to the surgery and follow-up care should be obtained.

GROUP I: PRE-OP MANIFEST ERROR ≤ 7 D

A) 1- 3 months post operation or last enhancement:

May be cleared for hire if asymptomatic and visual function is well within acceptable limits. The presence of significant symptoms or visual function that is at the limit of acceptability would warrant deferral and re-evaluation after 3 months.

B) 4-5 months post operation or last enhancement:

May be cleared for hire if asymptomatic and visual function is within acceptable limits. The presence of significant symptoms would warrant deferral and re-evaluation at 6 months post-op.

C) 6 months (or more) post operation or last enhancement:

May be cleared for hire if asymptomatic and visual function is within acceptable limits. However, a history of significant symptoms at or beyond 6 months post-op would warrant disqualification, regardless of current status.

GROUP II: PRE-OP MANIFEST ERROR > 7 D

May be cleared for hire if asymptomatic, visual function is within acceptable limits, and there is documentation that the manifest refraction has not changed by more than 0.5 D over the last six post-operative months. However, a history of significant symptoms at or beyond 6 months post-op would warrant disqualification, regardless of current status.

SUMMARY:

- All post-op records must be submitted for review;
- If pre-op manifest error 7 D, then acceptable for hire if at least 1 month post-op and no presence of significant symptoms. Defer for three months if significant symptoms are present; if present 6+ months post-op, disqualify;
- Acceptable only if pre-op manifest error > 7 D, acceptable if visual function is within acceptable limits, evidence that manifest refraction has not changed by more than .5 D over last 6 post-op months, and no history of significant symptoms.

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